

# PATENT COOPERATION TREATY

**PCT**

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C. 20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 16 March 2000 (16.03.00)	
<b>International application No.</b> PCT/US99/11940	<b>Applicant's or agent's file reference</b> UF-219XC1
<b>International filing date (day/month/year)</b> 28 May 1999 (28.05.99)	<b>Priority date (day/month/year)</b> 29 May 1998 (29.05.98)
<b>Applicant</b> DUNN, Ben, M. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
22 December 1999 (22.12.99)

☐ in a notice effecting later election filed with the International Bureau on:  
\_\_\_\_\_

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	<b>Authorized officer</b>  <p style="text-align: center;">S. Mafra</p> Telephone No.: (41-22) 338.83.38
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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>REP06298EP</b>	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. <b>PCT/US99/11940</b>	International filing date (day/month/year) <b>28/05/1999</b>	Priority date (day/month/year) <b>29/05/1998</b>
International Patent Classification (IPC) or national classification and IPC <b>A61K31/70</b>		
Applicant <b>UNIVERSITY OF FLORIDA et al.</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 7 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  <b>22/12/1999</b>	Date of completion of this report  <b>15.09.2000</b>
Name and mailing address of the international preliminary examining authority:   <b>European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465</b>	Authorized officer  <b>Giacobbe, S</b>  Telephone No. <b>+49 89 2399 8463</b>  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US99/11940

**I. Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

**Description, pages:**

1-17 as originally filed

**Claims, No.:**

1-15 as originally filed

**Drawings, sheets:**

1/7-7/7 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.  
☒ claims Nos. 1-15.

b. cause:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/11940

- ☒ the said international application, or the said claims Nos. 1-4 relate to the following subject matter which does not require an international preliminary examination (*specify*):

**see separate sheet**

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for the said claims Nos. 5-15.

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes:	Claims	2-4
	No:	Claims	1
Inventive step (IS)	Yes:	Claims	3,4
	No:	Claims	2
Industrial applicability (IA)	Yes:	Claims	see Separate Sheet
	No:	Claims	

### 2. Citations and explanations

**see separate sheet**

## VI. Certain documents cited

### 1. Certain published documents (Rule 70.10)

and / or

### 2. Non-written disclosures (Rule 70.9)

**see s parate sh et**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US99/11940

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**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

## **1. Section III**

1.1 Claims 1-4 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated *with respect to the industrial applicability* of the subject-matter of these claims (Article 34(4)(a)(i) PCT). However, although not required under the provisions of the PCT, an opinion will be given with respect to novelty and inventive step.

1.2 This IPEA agrees with the objection as to lack of unity put forward by the ISA. The present application consists of two inventions, respectively claimed in claims 1 and 5. As explained below, the use of a combination of AZT and 3TC for the treatment of FIS (Invention 1) is known in the art. Therefore, the common concept underlying the two inventions, namely the use of AZT in conjunction with a second nucleoside analogue, is not new, which leads to a lack of unity *a posteriori* of the present application. Since the Applicant, upon invitation, has not paid any additional fee, the present Opinion will be drawn only with respect of the invention first mentioned in the application, i.e. the invention for which a Search Report has been established. This invention, concerned with the use of AZT in conjunction with another nucleoside analogue, is contained in claims 1-4.

## **2. Section V**

### **2.1 Cited Documents**

The following documents (D) are referred to in this Opinion; the numbering will be adhered to in the rest of the procedure:

D1: WO 96 22778 A (UNIV EMORY) 1 August 1996

D2: WO 96 23509 A (MERCK & CO INC) 8 August 1996

D3: WO 97 49411 A (GLAXO GROUP LTD) 31 December 1997

D4: WO 96 30025 A (WELLCOME FOUND) 3 October 1996

D5: SMYTH N.R. ET AL: 'Susceptibility in cell culture of feline immunodeficiency virus to eighteen antiviral agents.' JOURNAL OF ANTIMICROBIAL CHEMOTHERAPY, 34/4, 1994, 589-594

### **2.2 Art 33(2) PCT (Novelty)**

The subject-matter of present claim 1 does not meet the requirements of Art 33(2)

PCT.

Document D1 discloses the use of a combination of a nucleoside analogue chosen among those described in claim 1 and e.g. AZT (cf. claim 8) for the treatment of FIV (cf. p. 8, l. 2). This document is therefore novelty-destroying for claim 1.

### **2.3 Art 33(3) PCT (Inventive step)**

2.3a The subject-matter of present claims 1 and 2 does not meet the requirements of Art 33(3) PCT.

The use of a combination of AZT and 3TC for the treatment of HIV is well known in the art, as acknowledged by the Applicant (cf. p. 2, ll. 19-24 of the description; see also the Abstracts of documents D2 and D3). Both these drugs are separately active on FIV (cf. document D4, p. 592, Table). On the other side, HIV and FIV are closely related diseases, to the point that 'FIV infections of domestic cats is considered to be an excellent small animal model for testing prophylactic and therapeutic strategies against AIDS viruses' (cf. description, p. 1, ll. 16 and 17). Therefore, the skilled person faced with the technical problem of finding new therapies for the treatment of FIV would be certainly led by these knowledges to the use of a combination as in present claims 1 and 2.

2.3b The subject-matter of present claims 3 and 4 meets the requirements of Art 33(3) PCT.

None of the available prior art documents suggests the combination of drug therapy, total body irradiation and bone marrow transplantation for the treatment of FIV.

**N.B.** It is observed that the use of a combination of AZT, 3TC and indinavir, a protease inhibitor, (Invention 2) is known in the art (see document D5, Abstract) for the treatment of HIV, which the Applicant has acknowledged as being a closely related disease (cf. description, p. 1). Lack of inventiveness of the second invention therefore results.

### **2.4 Art 33(4) PCT (Industrial applicability)**

As stated above, no opinion is given on the question of whether present claims 1-4 are industrially applicable since their patentability is *inter alia* dependent upon their formulation as well as upon national and regional laws and no unifying criteria is provided in this field by the PCT.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/US99/11940

**3. Section VI**

Certain published documents (Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
DE 197 03 131	30.7.98	29.1.97	
WO 99/55372	4.11.99	26.4.99	29.4.98
WO 99/66936	29.12.99	24.6.99	24.6.98

**4. Section VIII**

The expression 'another nucleoside analogue' used in claim 1 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claim unclear (Article 6 PCT).